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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,484	09/24/2003	Jerry A. Krill	1690-SPL	3976

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The Johns Hopkins University
Applied Physics Laboratory
11100 Johns Hopkins Road
Laurel, MD 20723-6099

EXAMINER

NATARAJAN, VIVEK

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/669,484	Applicant(s) KRILL, JERRY A.	
	Examiner Vivek Natarajan	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
4a) Of the above claim(s) 5-9 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 10-17 and 19-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/30/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

A medical capsule comprising the following types of payloads:

- A. A diagnostic microfluidics device (Spec. par.17, lines 1-8)
- B. A temperature-measuring device or microphone (par.17, lines 9-15)
- C. A means for expelling a medicament to treat a condition (par.19)
- D. A visualizing apparatus (par.20)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-2, 10-17, and 19-24 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Mr. Albert Fasulo on 9/19/05 a provisional election was made without traverse to prosecute the invention of Species A, Claims 3-4. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5-9 and 18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4 and 12-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Marshall (US Patent No. 6,632,175).

6. Regarding Claim 1, Marshall discloses a medical capsule 10 comprising a housing 12 enclosing a transceiver 62, and an ultrasonic transducer 66, a power supply 60, and a microprocessor 54 electrically connected to the transceiver (see Figs. 1 and 3 and the descriptions thereof in col.3, lines 39-57 and col.4, lines 34-48).

7. Regarding Claims 2-4, the housing has an interior space with a cargo bay area including a medical diagnostic device, particularly a microfluidic device (the Agilent 2100 bioanalyzer is one such device) for analyzing body fluids such as bile (see Fig. 9 and the description thereof in col.9, line 63 – col.10, line 30).

8. Regarding Claim 12, the housing 12 is readily ingestible within the digestive tract of the human body (col.3, lines 42-43).

9. Regarding Claim 13, the microprocessor 54 includes a signal interface to regulate communication between the payload 50 and the processing unit (col.4, lines 61-64).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 14-15 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Smith et al. (US Patent No. 5,515,853). Marshall discloses a system for wireless communication with a transceiver within a living body between a capsule 10 enclosing an ultrasonic communication module 66 connected to a transceiver 62, power supply 60, and microprocessor 54, and a remote transmitter/receiver 21 outside the body for transmitting and receiving ultrasound signals to and from the capsule (col.5, lines 44-49). Marshall further discloses a method of using the capsule communication system, including a step in which data is collected regarding a physiological condition within the body, after which the data is transmitted via an ultrasonic signal to an external transceiver outside the body (col.4, lines 1-33). Regarding Claim 15, Marshall also discloses that the capsule comprises a medical diagnostic device payload. Marshall does not utilize an omni-directional, two-way transducer array in the capsule, nor does he attach multiple spaced-apart external transceivers to the exterior surface of the body to continuously track the capsule's position. Smith discloses a three-dimensional ultrasound tracking system in which the position of a catheter within the body can be continuously monitored by attaching an

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omni-directional ultrasonic transducer array to the catheter's tip (col.13, lines 28-60).

Regarding Claims 19-24, Smith also discloses attaching multiple spaced-apart external transceivers to the outside of the body to track the position of the catheter (see Fig. 10 and col.3, lines 16-55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus and method disclosed by Marshall to include an omni-directional ultrasonic transducer array and by attaching multiple spaced-apart external transceivers to the exterior surface of the body as taught by Smith since this allows for more accurate, continuous tracking of the location of the capsule's position within the body.

12. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall as applied to Claim 1 above in view of Smith et al. and further in view of Bass et al. (US Patent No. 6,106,464). Marshall discloses a capsule including an ultrasonic communication module connected to a transceiver, power supply, and microprocessor, but does not mention including an array of at least six omni-directional ultrasonic transducers operable in the range of 5-20 MHz. Smith discloses a three-dimensional ultrasound tracking system in which the position of a catheter within the body can be continuously monitored by attaching an omni-directional ultrasonic transducer array to the catheter's tip. Smith also indicates that up to 32 transducers can be included in the array (col.3, lines 17-19). Bass teaches that in determining an optimal frequency for the transmission of ultrasound signals through the body, a tradeoff must be made between increased resolution and increased attenuation, such that the ultrasound frequency should be between 5-20 MHz. It would have been obvious to one

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having ordinary skill in the art at the time the invention was made to modify the medical capsule of Marshall by implementing an array of up to 32 omni-directional ultrasonic transducers as disclosed by Smith and to operate these transducers in the range of 5-20 MHz. as taught by Bass, since this allows for improved transmission of ultrasound signals between the capsule and the external transceivers.

13. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Smith et al. as applied to Claim 14 above, and further in view of Scarantino et al. (US Patent No. 6,402,689). Marshall in view of Smith discloses a system for ultrasonic wireless communication with a transceiver within a living body between a capsule enclosing an omni-directional ultrasonic transducer array connected to a transceiver, power supply, and microprocessor, and a remote transmitter/receiver outside the body. Marshall in view of Smith does not disclose using two or more capsules having means for ultrasonic communication with each other. Scarantino teaches a system of monitoring physiological parameters *in vivo* wherein an implantable sensor 50D communicates telemetrically with another implantable satellite sensor 50I, which in turn is telemetrically linked to an external receiver 75 (see Fig. 9 and the description thereof in col.24, line 62 – col.25, line 8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the capsule communication system disclosed by Marshall in view of Smith to include two or more sensory unit capsules in communication with each other as taught by Scarantino since this allows for increased data collection capability and efficiency.

14. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Smith et al. as applied to Claim 14 above in view of Christophersom et al. (Pub. No. US 2002/0123672 A1). Marshall in view of Smith discloses a system for ultrasonic wireless communication with a transceiver within a living body between a capsule enclosing an ultrasonic communication module 66 connected to a transceiver 62, power supply 60, and microprocessor 54, and a remote transmitter/receiver 21 outside the body (col.5, lines 44-49). Marshall does not indicate that the external transceiver 21 includes means for transmitting RF signals, nor does he provide a remote monitoring station for receiving these RF signals. Christophersom discloses an implantable medical device system comprising an implantable medical device 102, a means for transmitting RF signals 106 positioned external to the body, and a remote monitoring station 112 for receiving these RF signals (see Fig. 1 and the description thereof in pars.24-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the communication system as disclosed by Marshall to include a means for transmitting RF signals via an external transceiver and a means for receiving these RF signals at a remote monitoring station as taught by Christophersom, since this allows data to be communicated between the patient's body and a remote location such as a nurses' station outside the room.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vivek Natarajan whose telephone number is (571)272-6249. The examiner can normally be reached on Mon-Fri, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VN


ERIC F. WINAKUR
PRIMARY EXAMINER